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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,299	04/05/2005	Maxwell Edmund Whisson	05-296	3011
34704	7590	01/15/2009	EXAMINER	
BACHMAN & LAPOINTE, P.C. 900 CHAPEL STREET SUITE 1201 NEW HAVEN, CT 06510				VU, QUYNH-NHU HOANG
3763		ART UNIT		PAPER NUMBER
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				PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/530,299	WHISSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	QUYNH-NHU H. VU	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 January 2008.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-23 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-23, 25-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Response to Amendment***

This Office Action is replacing for previous Non-Final mailed on 7/25/08

Claims 16-23, 25-31 are present for examination.

Claims 1-15, 24 are cancelled.

### ***Specification***

This disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01 (o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb. 2000)).

Appropriate correction is required.

### ***Claim Objections***

Claim 18 is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner has objected to the claims for the reason set forth above in the objection to the specification. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16-23, 25-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Glazier et al.

(US 7,001,396).

Glazier discloses needle apparatus comprising: a thin wall sleeve 118; a tubular needle 160 having a distal end and a proximal end, the needle having a sharp point 22 at the distal end; and being hollow throughout its entire length, the sleeve 118 being mounted about the needle and the needle being closely engaged by the sleeve, the needle and the sleeve being longitudinally moveable relative to one another between a first position at which the needle extends from the sleeve (Figs. 2, 7); and a second position at which the sharp point is located within the sleeve (Figs. 3-4, 9), the needle remaining at least partially within the sleeve at all times; the needle 160 remaining in the fluid flow path of the apparatus at all times, a hub (including 120 and 134) is fixed mounted adjacent the proximal end of the needle; wherein the needle and the hub are capable of moving longitudinally together at all times, the needle extending from the hub so that the distal end of the needle is located externally of the hub, the sleeve 118 having the proximal end located within the hub and being slidably mounted relative to the hub; the distal end of sleeve located externally of the hub, the sleeve being unlatched in the first position and being latched in the second position

As noted that the limitation "the sleeve being arranged to enter the incision such that after the tissue has been pierced...when the needle has been withdrawn to the second position" is the method for operating the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

Examiner treats the limitation above as a functional limitation. And the device of Glazier is capable of performing this function.

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As to claims 17, 29, 31, the claim further limits the method of operating or functionality of the apparatus of claims 16 and 28 (see rejection below) but does not provide any structure limitations. As such, the device of Glazier is reasonably capable of withdrawing the sleeve from the tissue by application of further longitudinal traction to the hub.

As to claims 18-19, 21-23, the projection 124 and means is provided for positively engaging the projection in the second position so as to latch the sleeve (Figs. 3-4, 9); fingers 127 are located within the hub.

As to claim 25, it is inherent in the device of Glazier that pressure is applied directly to sleeve from surround tissue upon insertion and retraction from a body. This limitation in claim 25 is also functional limitation.

As to claims 26-27, they encompass the same scope of the invention as to that of apparatus claims except they are drafted in method format instead of apparatus format. The claims are therefore rejected for the same reason as set forth above.

As to claims 28-29, Glazier discloses the claimed invention, as discussed above. Glazier further discloses a catheter introducer comprising a sheath 140.

As noted that the limitation "the sleeve which enters the tissue simultaneously with the sleeve, such that after the tissue has been pierced...as a result of the pressure applied radially by surrounding tissue to the sheath" is the method for operating the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

Examiner treats the limitation above as a functional limitation. And the device of Glazier is capable of performing this function.

Claims 16-19, 21-23, 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Prestidge et al. (US 6,626,868).

Prestidge discloses a needle apparatus, in Figs. 23-25, 44-45, comprising: a thin wall sleeve 18; a tubular needle 20 having a distal end and a proximal end, the needle having a sharp point 22 at the distal end; and being hollow throughout its entire length, the sleeve 18 being mounted about the needle

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and the needle being closely engaged by the sleeve, the needle and the sleeve being longitudinally moveable relative to one another between a first position at which the needle extends from the sleeve (Figs. 23-24, 44); and a second position at which the sharp point is located within the sleeve (Figs. 25, 45), the needle remaining at least partially within the sleeve at all times; the needle 20 remaining in the fluid flow path of the apparatus at all times, a hub 12, 16 or (366 of Fig. 45) is fixed mounted adjacent the proximal end of the needle; wherein the needle and the hub are capable of moving longitudinally together at all times, the needle extending from the hub so that the distal end of the needle is located externally of the hub, the sleeve 18 having the proximal end located within the hub and being slidable mounted relative to the hub; the distal end of sleeve located externally of the hub, the sleeve being unlatched in the first position and being latched in the second position

As noted that the limitation "the sleeve being arranged to enter the incision such that after the tissue has been pierced...when the needle has been withdrawn to the second position" is the method for operating the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

Examiner treats the limitation above as a functional limitation. And the device of Prestidge is capable of performing this function.

As to claim 17, the claim further limits the method of operating of functionality of the apparatus of claim 16 but does not provide any structure limitations. As such, the device of Prestidge is reasonably capable of withdrawing the sleeve from the tissue by application of further longitudinal traction to the hub.

As to claims 18-19, 21-23, the projection 362 and means is provide for positively engaging the projection in the second position so as to latch the sleeve (Fig. 45).

As to claim 25, it is inherent in the device of Prestidge that pressure is applied directly to sleeve from surround tissue upon insertion and retraction from a body. This limitation in claim 25 is also functional limitation.

As to claims 26-27, they encompass the same scope of the invention as to that of apparatus claims except they are drafted in method format instead of apparatus format. The claims are therefore rejected for the same reason as set forth above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prestidge.

Prestidge disclose the claimed invention. Prestidge does not clearly mention that the projection 362 is formed of a disc. It would have been an obvious matter of design choice to provide a projection in formed of a disc, since applicant has not disclosed that disc-shaped solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with projection of prior art.

Also, Applicant admitted that the disc can be formed with different shapes (page 3, line 14 of Specification).

Claims 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prestidge in view of O'Laughlin (US 5,295,974).

Prestidge discloses the invention substantially as claimed. Prestidge does not disclose a sheath in the catheter introducer device.

O'Laughlin discloses a needle apparatus comprising: a needle 49, a sleeve 47 and a sheath 52 can be acted as a guide for introduction.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Prestidge with a sheath, as taught by O'Laughlin, in order to protect the cannula/needle and to avoid accidental sticking of the user or another person.

As noted that the limitation "the sleeve which enters the tissue simultaneously with the sleeve, such that after the tissue has been pierced...as a result of the pressure applied radially by surrounding

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tissue to the sheath" is the method for operating the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

Examiner treats the limitation above as a functional limitation. And the device of Prestidge in view of O'Laughlin is capable of performing this function.

***Response to Arguments***

Applicant's arguments with respect to claims 1-23, 25-31 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
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